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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,027	10/27/2000	Jonathan L. Sessler	4201.01 US	6781

32270 7590 02/03/2003

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/699,027	Applicant(s) Sessler
	Examiner David Lukton	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 13, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) *1-19 and 25-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *20, 21, and 23* is/are rejected.

7) ☒ Claim(s) *22 and 24* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' species elections (paper No. 9) are acknowledged:

(a) motexafin gadolinium as the agent that accumulates in neoplastic tissue in accordance with claim 20, step (a);

(b) ascorbate as the cellular metabolite in accordance with claim 20, step (a);

(c) ascorbate as the cellular metabolite in accordance with claim 20, step (c)

(d) ionizing radiation is not required.

. . . .

Claims 20-24 are examined in this Office action; claims 1-19 and 25-27 remain withdrawn from consideration.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 20 and 23 are rejected under 35 U.S.C. §103 as being unpatentable over Sessler (USP 5622946) in view of Lehninger (Biochemistry, 2nd Edition, pages 641-642 Worth Publishers, 1975).

Sessler discloses a method of inducing oxidative stress by administering a compound that meets the requirements of instant claim 20, step (a). Sessler does not disclose the concommitant (or subsequent) administration of a "precursor" of ascorbic acid, as required by claim 20, step (c).

Lehninger discloses the biosynthetic pathway of ascorbic acid. As is evident, molecular oxygen and water are both integral "agents" in the biosynthesis of ascorbic acid. For example, the enzyme gulonolactone oxidase requires molecular oxygen in order to oxidize gulonolactone to ascorbic acid. As such, oxygen and water are both "precursors" of ascorbate. Lehninger makes no mention of texaphyrins.

A practioner of the Sessler invention would recognize that during administration of the texaphyrin to a mammalian subject, that subject will inevitably be consuming oxygen. Morever, the practioner would have ample motivation to abstain from preventing the animal from consuming oxygen. As for water, the fact is that aqueous vehicles are the

most common for i.v. administration of drugs. Thus, (a) consumption of molecular oxygen (by the test animal) during (and subsequent to) administration of the texaphyrin would be inevitable, and (b) co-adminstration of the texaphyrin with water would have been obvious. In the mind of the "ordinarily skilled artisan", the reason for using these "precursors" of ascorbic acid may well have been different from that espoused by applicants. But what matters is whether the limitations of the claims are met, not the reasons for meeting them.

Thus, it would have been obvious to one of ordinary skill to administer a "precursor" of ascorbic acid concommitant with (or subsequent to) administration of a texaphyrin.

*

Claims 20, 21 and 23 are rejected under 35 U.S.C. §103 as being unpatentable over Vogel (USP 5,244,671).

Vogel disclose the use of photactivatable porphycenes. Also disclosed (e.g., col 6, line 66) is the production of singlet oxygen following irradiation. Also disclosed (col 7, line 32) is the co-adminstration of the porphycenes.

Thus, the limitations of steps (a) and (c) are met; instant claim 20 does not preclude the possibility of that step (a) includes ascorbic acid, nor does claim 20 preclude the possibility that step (c) includes the "agent" that catalyzes the production of reactive oxygen species.

Thus, the claims are rendered obvious.

*

Claims 20, 21 and 23 are rejected under 35 U.S.C. §103 as being unpatentable over Platzek (USP 6,136,841).

Platzek discloses the use of porphyrins for photodynamic therapy. Also disclosed (col 7, line 57) is the co-administration of the porphyrin with ascorbic acid.

Thus, the limitations of steps (a) and (c) are met; the claims are rendered obvious.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800